



CHEST *Physician*

THE NEWSPAPER OF THE AMERICAN COLLEGE OF CHEST PHYSICIANS



COURTESY COOPER CLINIC

The risk of lung cancer was reduced 68% in men with the highest level of cardiorespiratory fitness, a large study suggests.

Fitness levels may predict cancer risk

BY PATRICE WENDLING
IMNG Medical News

Measured levels of cardiorespiratory fitness appear to be as predictive of cancer risk and survival as they are of heart disease risk and survival, according to a 20-year, prospective study of more than 17,000 men.

The risks of lung and colorectal cancer were reduced 68% and 38%, respectively, in men with the highest level of cardiorespiratory fitness, compared with those who were the least fit.

Cardiorespiratory fitness did not significantly reduce prostate cancer risk, but the risk of dying was significant-

ly lower among men with prostate, lung, or colorectal cancer if they were more fit in middle age ($P < .001$).

Prior studies have shown that being physically active is protective against cancer, but this study is unique because it looked at a very specific marker – cardiorespiratory fitness as measured by maximal exercise tolerance testing, Dr. Susan G. Lakoski said during a briefing highlighting research at the upcoming American Society of Clinical Oncology meeting.

“Fitness as formal measurement is known to prevent cardiovascular disease, and it’s also known that it

See **Exercise** • page 7

SLEEP STRATEGIES: Apnea, obesity often mix in an alarming way

Meet ‘obesity hypoventilation syndrome.’

Obesity, as defined by a body mass index greater than 30 kg/m², has become a global epidemic and one of the leading causes of disability around the world.

If the obesity trend continues, it is projected that 65 million additional obese patients will live in United States by 2030 (Wang et al. *Lancet* 2011;378[9805]: 815). The problem has become so severe that medicine has had to develop two additional terms to describe progressive obesity: morbid obesity (BMI > 40 kg/m²) and super obesity (BMI > 50 kg/m²); the prevalence of both of these conditions is also increasing at an

alarming rate.

Obesity hypoventilation syndrome (OHS) is a condition defined by the concomitant existence of obesity, daytime hypercapnia (PCO₂ > 45 mm Hg), and sleep-disordered breathing, most commonly in the form of obstructive sleep apnea (OSA), in the absence of any other cause of CO₂ retention (eg, obstructive or restrictive lung disease, neuromuscular weakness, or hypothyroidism). Given the dramatic increase in the prevalence of obesity, it is reasonable to assume that the prevalence of OHS is also on the rise. The exact

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COMMENTARY: What’s new in HIPAA?

BY JOSEPH S. EASTERN, M.D.

I’m hearing a lot of concern about the impending changes in the Health Insurance Portability and Accountability Act (HIPAA) – which is understandable, since the Department of

Health and Human Services has presented them as “the most sweeping ... since [the Act] was first implemented.”

But after a careful perusal of the new rules – all 150 three-column pages of them – I can say with a modest degree of confidence that

for most physicians, compliance will not be as challenging as some (such as those trying to sell you compliance-related materials) have warned.

However, you can’t simply ignore the new regulations;

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Have we come far enough in PAH patient outcomes?

CHANGEVI

Despite advances, patients' long-term outcomes remain poor

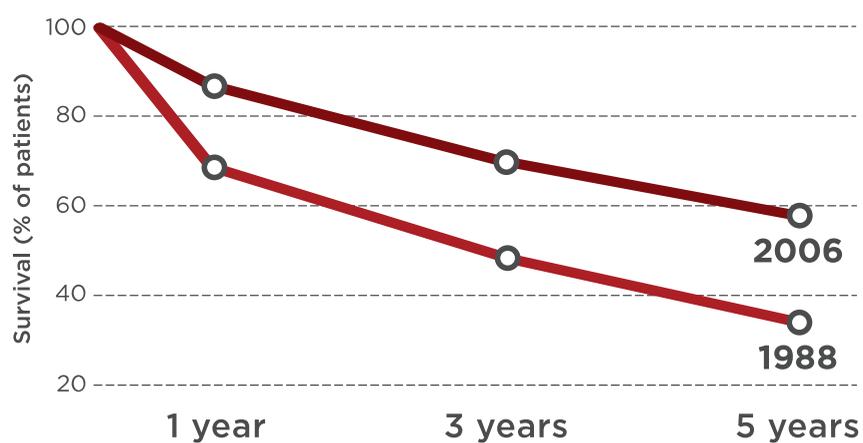
Significant progress has been made in PAH treatment over the past 2 decades, yet patient morbidity and mortality remain high.¹ There is limited information on the long-term effects of PAH-specific therapies, and many patients continue to experience death, hospitalizations, and the need for additional therapies.^{1,2}

Now is the time for a new perspective in PAH. Experts are calling for future PAH studies to deliver data on the long-term effect of therapy on clinical outcomes, such as hospitalizations and mortality.¹⁻³ Actelion is committed to investigating this evolving perspective in PAH.

References: 1. Galiè N, Manes A, Negro L, Palazzini M, Bacchi-Reggiani M, Branzi A. A meta-analysis of randomized controlled trials in pulmonary arterial hypertension. *Eur Heart J*. 2009;30:394-403. 2. Gombert-Maitland M, Dufton C, Oudiz RJ, Benza RL. Compelling evidence of long-term outcomes in pulmonary arterial hypertension? *J Am Coll Cardiol*. 2011;57:1053-1061. 3. McLaughlin VV, Badesch DB, Delcroix M, et al. End points and clinical trial design in pulmonary arterial hypertension. *J Am Coll Cardiol*. 2009;54:S97-S107. 4. Thenappan T, Shah SJ, Rich S, Gombert-Maitland M. A USA-based registry for pulmonary arterial hypertension: 1982-2006. *Eur Respir J*. 2007;30:1103-1110. 5. D'Alonzo GE, Barst RJ, Ayres SM, et al. Survival in patients with primary pulmonary hypertension. Results from a national prospective registry. *Ann Intern Med*. 1991;115:343-349.

PERPECTIVE

Survival in PAH, 1988 and 2006*^{4,5}



*Survival observed over periods from 1981-1988 and 1982-2006, respectively.



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Heads up: New HIPAA requirements

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definitions will be more complex, security breaches more liberally defined, and potential penalties will be stiffer. Herewith, the salient points:

► **Business associates.** The criteria for identifying “business associates” (BAs) remain the same: nonemployees, performing “functions or activities” on behalf of the “covered entity” (your practice), that involve “creating, receiving, maintaining, or transmitting” personal health information (PHI).

Typical BAs include answering and billing services, independent transcriptionists, hardware and software companies, and any other vendors involved in creating or maintaining your medical records. Practice management consultants,

attorneys, companies that store or microfilm medical records, and record-shredding services are BAs if they must have direct access to PHI to do their jobs.

Mail carriers, package-delivery people, cleaning services, copier repairmen, bank employees, and the like are *not* considered BAs, even though they might conceivably come in contact with PHI on occasion. You are required to use “reasonable diligence” in limiting the PHI that these folks may encounter, but you do not need to enter into written BA agreements with them.

Independent contractors who work within your practice – aestheticians and physical therapists, for example – are not considered BAs either, and do not need to sign a BA agreement; just train them, as you do your employees.

What is new is the additional onus placed on physicians for confidentiality breaches committed by their BAs. It’s not enough to simply have a BA contract. You are expected to use “reasonable diligence” in monitoring the work of your BAs. BAs and their subcontractors are directly responsible for their own actions, but the primary responsibility is ours.

Let’s say that a contractor you hire to shred old medical records throws them into a trash bin instead; under the new rules, you must assume the worst-case scenario. Previously, you would have to notify affected pa-

tients (and the government) only if there was a “significant risk of financial or reputational harm,” but now, any incident involving patient records is assumed to be a breach, and must be reported. Failure to do so could subject your practice, as well as the contractor, to significant fines – as high as \$1 million in egregious cases.

► **New patient rights.** Patients will now be able to restrict the PHI shared with third-party insurers and health plans if they pay for the services themselves. They also have the right to request copies of their electronic health records, and you can bill the actual costs of responding to such a request. If you have EHR, now might be a good time to work out a system for doing this, because the response time has been decreased from 90 to 30 days – even less in some states.

► **Marketing limitations.** The new rule prohibits third-party-funded marketing to patients for products and services without their prior written authorization. You do not need prior authorization to market your own products and services, even when the communication is funded by a third party, but if there is any such funding, you will need to disclose it.

► **Notice of privacy practices (NPP).** You will need to revise your NPP to explain your relationships with BAs, and their status under the new rules. You will need to explain the breach notification process, too, as well as the new patient rights mentioned above. You must post

your revised NPP in your office, and make copies available there, but you need not mail a copy to every patient.

► **Get on it.** The rules specify Sept. 23 as the effective date for the new regulations, although you have a year beyond that to revise your existing BA agreements. Extensions are possible, even likely.

Dr. Eastern practices dermatology and dermatologic surgery in Belleville, N.J. He writes about practice management for IMNG Medical Media.

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VIEW ON THE NEWS

Dr. Stuart M. Garay, FCCP,

comments: While the business of medicine continues to get tougher, so do the rules regulating this business. Privacy issues continue to draw significant scrutiny by the public at large as well as the government. The Health Insurance Portability and Accountability Act (HIPAA) has been upgraded with new regulations: Definitions are more complex, security breaches are more broadly defined, and the potential penalties are greater. Don’t ignore these new rules. Neither ignorance nor delay is a legitimate excuse.



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Telavancin gets nosocomial pneumonia indication

Only S. aureus infections tagged in new approval.

BY ELIZABETH MEHCATIE

IMNG Medical News

The lipoglycopeptide antibiotic telavancin has been approved for treating patients with hospital-acquired or ventilator-associated bacterial pneumonia caused by susceptible isolates of *Staphylococcus aureus*, the Food and Drug Administration has announced.

Telavancin, marketed as Vibativ by Theravance, “should be used for the treatment of HABP/VABP only when alternative treatments are not suitable,” the FDA said in a June statement announcing the approval.

Among those patients with pre-existing kidney disease, mortality was higher for those taking telavancin – information that is now included in the boxed warning for telavancin.

It is not approved to treat other bacteria that cause pneumonia, the statement pointed out. It is administered once a day.

Approval of the expanded indication was based on the safety and effectiveness of telavancin in two studies of 1,532 patients with HABP/VABP, which compared treatment with telavancin to vancomycin, according to the FDA.

In a statement, the manufacturer said that, in the two noninferiority studies, ATTAIN I and ATTAIN II, patients received either telavancin (10 mg/kg IV once a day) or vancomycin (1 g IV every 12 hours).

All-cause mortality 28 days after treatment started was comparable between the two groups, but among those patients with pre-existing kidney disease, mortality was higher for those taking telavancin – information that is now included in the boxed warning for telavancin, according to the FDA.

The most common adverse effect associated with treatment in the trials was diarrhea.

Telavancin should be considered for patients with pre-existing moderate to severe renal impairment (creatinine clearance of 50 mL/min or less) “only when the anticipated benefit to the patient outweighs the potential risk,” according to Theravance.

Telavancin was initially approved in 2009 as a treatment for complicat-

ed skin and skin structure infections caused by susceptible isolates of gram-positive bacteria, including

both methicillin-susceptible (MSSA) and methicillin-resistant (MRSA) strains of *S. aureus*, with a boxed warning about the fetal risks of treatment.

In a statement, the company said

that telavancin would be made available to wholesalers for purchase for the pneumonia indication in the third quarter of 2013.

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FDA: No starch solutions for critically ill, CPB patients

BY ELIZABETH MEHCATIE
IMNG Medical News

The Food and Drug Administration is warning that hydroxyethyl starch solutions should no

longer be used in the treatment of critically ill adult patients – including patients with sepsis and those admitted to an intensive care unit – after completing an analysis of data that found an increase in the risk of

death and renal injury in these groups.

In a statement, the agency also recommended that the use of hydroxyethyl starch (HES) solutions, used as plasma volume expanders, be avoid-

ed in patients who are having open heart surgery with cardiopulmonary bypass (CPB), because of an increased risk of excessive bleeding.

The FDA is making these recommendations after completing an analysis of data from randomized controlled trials, meta-analyses, and observational studies in thousands of critically ill patients, and from a meta-analysis of 18 randomized controlled trials of almost 1,000 patients undergoing open heart surgery with cardiopulmonary bypass.

The data on critically ill adults included three double-blind, multicenter, randomized controlled studies published in 2012, which compared HES with saline solution or Ringer's acetate, in patients with severe sepsis (two studies), or patients in the ICU who had sepsis, had undergone elective surgery, and had an APACHE II score of at least 25. In these studies, which monitored patients for 90 days, HES was associated with increased mortality and/or renal injury requiring RRT, the FDA statements said. The results of meta-analyses and observational studies in similar populations lend additional support to these findings, the statement added.

In the meta-analysis of studies of patients undergoing open heart surgery with cardiopulmonary bypass, the “use of different HES products, irrespective of molecular weight or degree of molar substitution, was associated with increased bleeding,” according to the statement. The meta-analysis was published in 2012 (*J. Thoracic Cardiovasc. Surg.* 2012;144;223-30).

A boxed warning about the risk in ICU and septic patients is being added to the labels of HES products, and the information about the excessive bleeding risk in open heart surgery patients is being added to the warnings and precautions section.

There are four FDA-approved HES products for treating and preventing hypovolemia: HESPAN (6% HES 450/0.7^a in sodium chloride injection); Hetastarch (6% in 0.9% sodium chloride injection), a generic equivalent of Hesperan; Hextend (6% HES 450/0.7 in physiologic solution); and Voluven (6% HES 130/0.4 in normal saline).

The advisory is available at fda.gov/BiologicsBloodVaccines/SafetyAvailability/ucm358271.htm. Adverse events related to HES solutions should be reported to the FDA's MedWatch program at fda.gov/Safety/MedWatch/HowToReport/default.htm or 800-332-1088.

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Fitness may predict cancer risk

Exercise from page 1

helps in terms of survival risk; but what hasn't been known is, Does it prevent incident cancer and mortality after cancer diagnosis? That's what's elucidated in the current study," said Dr. Lakoski, director of the cardiovascular prevention program for cancer patients at the University of Vermont, Burlington.

She noted that several organizations, including the President's Council on Fitness, Sports & Nutrition, are trying to measure fitness formally and that the American Heart Association has issued policy statements that fitness should be measured and normative values developed to determine cardiovascular risk.

"Fitness is a formal measurement: It's sort of like measuring your LDL cholesterol; you get a very specific number to target," Dr. Lakoski said. "When you ask someone about their physical activity, you don't get that information."

The 17,049 men in the study underwent exercise tolerance testing with a treadmill or bicycle and risk factor assessment at an average age of 50 years as part of the Cooper Center Longitudinal Study in Dallas. Metabolic equivalents (METs) were used to record the men's cardiorespiratory fitness (CRF) and to place

them into five CRF quintiles. Lung, colorectal, and prostate cancers were assessed using Medicare claims data



A single MET increase reduced the risk of dying from cancer by 14% in the study of more than 17,000 men.

DR. LAKOSKI

at Medicare age, and cause-specific mortality was determined after cancer diagnosis.

Over the 20 years of follow-up, 2,885 men were diagnosed with prostate, lung, or colorectal cancer, and 769 of them died.

Compared with men in the lowest CRF quintile, hazard ratios (HR) for incident lung, colorectal, and prostate cancer among men in the highest quintile were 0.32 ($P < .001$), 0.62 ($P = .05$), and 1.13 ($P = .14$), after researchers adjusted for such risk factors as smoking, body mass index, and age, Dr. Lakoski reported.

In men who developed cancer, both cancer-specific mortality and cardiovascular-specific mortality declined across increasing CRF quintiles

($P < .0001$).

Even a single MET increase reduced the risk of dying from cancer and cardiovascular disease by 14% and 23%, respectively (HR, 0.86; HR, 0.77; $P < .001$ for both measures), Dr. Lakoski said.

Another striking finding is that even if men aren't obese, they still have an increased risk of cancer if they aren't fit, "which suggests that everyone can benefit from improving their fitness," Dr. Sandra Swain, ASCO president and medical director of the Washington (D.C.) Cancer Institute, told reporters.

"The findings make clear that patients should be advised that they need to achieve a certain fitness level, and not just be told that they need to exercise," Dr. Swain noted in a statement.

"Fitness is a key risk factor for survival, and based on this study, an important factor to measure to assess future cancer risk and prognosis in men," Dr. Lakoski said in an interview.

The study did not evaluate whether a particular type of exercise contributed more consistently to cardiovascular fitness, but in general, activities performed at high intensity, regardless of type, are the best way to improve fitness, she said.

More research is needed to determine fitness and cancer risk in women, and fitness and risk of all major site-specific cancers, Dr. Lakoski observed.

She reported having no relevant financial disclosures.

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VIEW ON THE NEWS

Dr. Darcy D. Marciniuk, FCCP, comments: In this 20-year longitudinal observational cohort, high levels of fitness in men were associated with adjusted risk reductions of 68% in lung cancer and 38% in colorectal cancer incidence. The magnitude of those associations and the concordant objective reduction in mortality are truly impactful, particularly for two common and deadly malignancies.

If these results (which were formally documented by cardiopulmonary exercise test) were noted with any other intervention, it would (deservedly so) be front page news!

The message is clear: It is time for all physicians to get or stay fit, and importantly, actively enable our patients to do the same. Let's save some lives!



Annual PAH screening recommended for systemic sclerosis

BY MITCHEL L. ZOLER
IMNG Medical News

MADRID – Patients with systemic sclerosis should undergo annual screening for pulmonary arterial hypertension using a combination of transthoracic echocardiography and pulmonary function tests, an international expert panel said.

These are the first evidence- and consensus-based recommendations for pulmonary arterial hypertension (PAH) screening in patients with systemic sclerosis, and the panel also called for screening patients with mixed or other connective tissue diseases with scleroderma features. "About 5%-15% of patients with systemic sclerosis develop PAH, and once PAH occurs, up to 30% of patients will die within 3 years, Dr. Dinesh Khanna said at the annual European Congress of Rheumatology.

In an interview, Dr. Khanna, director of the scleroderma program at the University of Michigan, Ann Arbor, said that despite there being approved

drugs to treat systemic sclerosis and other scleroderma-spectrum disorder connective tissue diseases, these treatments "have not had a huge impact on survival. The only thing we can offer patients is screening, followed by early diagnosis and treatment."

The new recommendations say that patients with a tricuspid regurgitant velocity measured by transthoracic echocardiography greater than 2.8 m/s require assessment for PAH by right heart catheterization. Right heart catheterization is also needed for patients with a tricuspid regurgitant velocity of 2.5-2.8 m/s if they also have signs or symptoms of PAH such as dyspnea, fatigue, chest pain, dizziness, loud pulmonary sound, or peripheral edema. The key measures on pulmonary function tests that trigger right heart catheterization is a forced vital capacity (FVC) to diffusion capacity of lungs for carbon monoxide (DLCO) ratio of more than 1.6, or a DLCO of less than 60% if either appears in the setting of PAH signs or symptoms. Alternative-

ly, meeting either of these pulmonary criteria should lead to right heart catheterization regardless of signs and symptoms if the patient's most recent blood level of N-termi-



About 5%-15% of patients with systemic sclerosis develop PAH, and up to 30% of PAH patients will die within 3 years.

DR. KHANNA

nal pro-brain natriuretic peptide (NT-ProBNP) was greater than twice the upper limit of normal.

The panel also said patients should undergo right heart catheterization regardless of PAH signs if they fulfill the screening algorithm developed for the DETECT study (Ann. Rheum. Dis. 2013 May 18 [doi:10.1036/anr-rheumdis-2013-203301]).

The panel recommended annual transthoracic echo and pulmonary

function test screening, or more frequently if a patient shows new signs or symptoms. Measurement of NT-ProBNP should happen at baseline, and then be repeated if new signs or symptoms of PAH appear. They also recommended applying the full DETECT screening algorithm in patients diagnosed with systemic sclerosis or other scleroderma spectrum connective-tissue disease for more than 3 years and a DLCO that is less than 60%. Right heart catheterization is mandatory to definitively diagnose PAH, Dr. Khanna stressed. The panel also said screening is not needed in patients with mixed- or other connective tissue disorders who did not have scleroderma-like features.

The task force was supported by the Scleroderma Foundation and the Pulmonary Hypertension Association. Dr. Khanna has been a consultant to several drug companies including Actelion, Bayer, Genentech/Roche, Gilead, Merck, and DIGNA.

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Postop program puts dent in pulmonary complications

BY MARY ANN MOON

IMNG Medical News

A multidisciplinary postoperative care program of patient and staff education, early patient mobilization, and pulmonary interventions has begun to reduce the excessive rate of postsurgical pulmonary complications at a large urban safety-net hospital, according to a report in *JAMA Surgery*.

"We are eager to monitor our outcomes over a longer period, and we are stimulated by the possibility that postoperative complications may be diminished by adherence to simple, inexpensive, easily performed patient care strategies," said Dr. Michael R. Cassidy of the department of surgery, Boston University Medical Center, and his associates.

When data collected in the National Surgical Quality Improvement Program revealed that their center "was

Before I COUGH, 80% of 250 patients were in bed at the time of the audit, with only 19.6% seated in a chair or walking. After I COUGH, 69.1% of 250 patients were out of bed.

a high outlier for all measured postoperative pulmonary complications," the investigators formed a multidisciplinary group to address the problem. "It was disturbing to discover that our hospital was a high outlier in all NSQIP-defined adverse pulmonary outcomes, but we regarded this as an opportunity to improve care," they said.

BUMC is the largest safety-net facility in New England. The annual income of more than half of its patients is below \$20,420, approximately 25% of its patients do not speak English, and 70% belong to racial or ethnic minorities, the investigators noted.

VITALS

Major finding: Before I COUGH, 52.8% of patients had an incentive spirometer within reach; an unknown number were using it appropriately. Afterward, 77.2% had the device within reach and were using it appropriately.

Data source: A comparison of postoperative complications between 250 patients hospitalized before I COUGH was implemented and 250 hospitalized afterward.

Disclosures: The investigators reported having no financial conflicts of interest.

The committee included representatives from the hospital's departments of surgery, nursing, and quality improvement, as well as from the units on respiratory therapy, preoperative assessment, infection control, and physical therapy. To devise a program to reduce the incidence of adverse pulmonary complications, these members reviewed the sparse literature regarding prevention of postoperative pneumonia and audited postsurgical pulmonary practices at their medical center.

The audit found that patients received no formal preoperative education about the importance of lung expansion, mobility, and other strategies to prevent pulmonary complications, and that families usually weren't included in whatever minimal education did take place. In addition, physicians' orders for nurses regarding postoperative pulmonary care "were irregular or absent."

The program that was then developed was given the acronym "I COUGH" to help physicians, nurses, patients, and families remember its key principles: Incentive spirometry, Coughing and deep breathing, Oral care, Understanding, Getting out of bed frequently, and Head-of-the-bed elevation. It was intended for all patients on the general surgery and vascular surgery services.

I COUGH included brochures, a video, and posters to educate patients, families, nurses, and physicians about the importance of pulmonary care. Proper use of incentive spirometry was demonstrated, the use of mouthwash and toothbrushing was recommended at least twice a day, and elevation of the head of the bed to at least 30 degrees was advocated. All this information was reinforced at preoperative clinic visits and in the preoperative holding area just before surgery. Nursing staff also reiterated the information after the procedures, as did surgeons, attending physicians, and house staff during rounds.

The effort also included standardized electronic physician order sets with "specific and detailed orders for all elements of the I COUGH program." These included instructions for patients to perform deep breathing and coughing every 2 hours; for patients to perform incentive spirometry 10 times every hour while awake; for nurses to document incentive spirometry volume every 4 hours and to ensure that the head of the patient's bed was elevated to at least 30 degrees; for patients to walk at least once on the day of operation unless contraindicated; and for patients to get out of bed and sit in a chair for a while at least 3 times per day.

Dr. Cassidy and his associates then compared data collected during the year before I COUGH was implemented to that collected during the year afterward.

Before I COUGH, 80% of 250 patients were in bed at the time of the audit, with only 19.6% seated in a chair or walking. After I COUGH, 69.1% of 250 patients were out of bed. Before I COUGH, only 52.8% of patients had an incentive spirometer within reach and an unknown number were using it appropriately, whereas afterward 77.2% of patients had the device within reach and were using it appropriately. Both findings were statistically significant.

The incidence of postoperative pneumonia was 2.6% before I COUGH, which dropped to 1.6% in the year afterward ($P = .09$). Similarly, the incidence of unplanned intubations was 2.0% before I COUGH, which decreased to 1.2% afterward, the authors reported (*JAMA Surg*. 2013 June 5 [doi: 10.1001/jamasurg.2013.358]).

These successes are due in part to the involvement of the multidisciplinary team at all stages of development of the I COUGH program, the investigators said.

"We have not imposed a standard of care by mandate, but instead have involved nursing leadership and practicing ward and ICU nurses in the process of redefining the culture.

"We found that involvement of

'We found that involvement of representatives of each discipline significantly increased acceptance of the I COUGH program, and instilled a sense of commitment and pride.'

representatives of each discipline significantly increased acceptance of the I COUGH program, and instilled a sense of commitment and pride that could not have been achieved by simply instituting and enforcing a policy without input from all parties involved," Dr. Cassidy and his colleagues added.

While the study had several limitations, including variations in data-gathering techniques and NSQIP reporting protocols, the investigators pointed to "substantial differences in nursing practice documented between the audits before and after I COUGH implementation."

"We believe that a favorable change in practice occurred as a result of our program," they wrote.

VIEW ON THE NEWS

Steven Q. Simpson, FCCP, comments:

This article illustrates some key points about quality improvement and patient outcomes. First, it is not rocket science, i.e., the interventions can be simple, yet potent. Second, it requires inter-professional teamwork. And third, it requires measuring and accepting that our care is not as good as we thought it was, along with measuring to see whether the changes we make are just change or change for the better. The sorts of efforts taken by these authors can be undertaken in any hospital, large or small, and for any clinical problem.

The authors set an excellent example for us all.



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Cardiac rehab benefits elderly heart failure patients

BY MITCHEL L. ZOLER
IMNG Medical News

ROME – A multiweek program of cardiac rehabilitation is as beneficial in elderly patients with chronic heart failure as it is in younger heart failure patients, according to a review of 243 patients at one Belgium center.

“Although they have lower exercise capacity at baseline, older patients have at least as much benefit from an exercise program as younger patients with chronic heart failure,” Sofie Paradaens reported in a poster at the annual meeting of the European Association for Cardiovascular Prevention and Rehabilitation. She is a physiotherapist and PhD student in the department of internal medicine at Ghent (Belgium) University.

Ms. Paradaens and her associates’ assessment of cardiac rehabilitation relative to a patient’s age included 243 patients who participated in a rehabilitation program at Ghent University, who had chronic heart failure, and

who had an amino-terminal pro-B-type natriuretic peptide value of at least 400 pg/mL, a level very suggestive of heart failure (Circulation 2011;123:2015-9). The group included 43 patients (18%) who were at least 75 years old (average, 78 years) and 68 patients younger than 60 (average, 51 years), with the remaining 132 patients evenly distributed across the range of 60-74 years old.

All participants had just been hospitalized, for an ACS event, cardiac surgery, or heart failure.

The hospital-based rehabilitation program combined aerobic and strength training, and was designed to bring a patient’s heart rate to his anaerobic threshold during each session. Sessions occurred two or three times a week, and the full program included 45 sessions over a period of 4-5 months. The patients studied averaged 34 sessions each; patients aged 75 or older averaged 32 sessions each, while those younger than 60 averaged 35 sessions each.

The researchers measured peak exercise capacity using cardiopulmonary exercise testing at baseline and at the end of the rehabilitation session sequence, and found that the 16% average level of improvement among patients at least 75 years old closely matched the average 19% improvement among the patients younger than 60, and the 17% average improvement among everyone else, Ms. Paradaens and her associates reported. All age groups also showed

similar improvements in their average ventilatory equivalence ratio, as well as their average 6-minute walk distance; however, the 29% average increased distance among patients younger than 60 years significantly exceeded the 19% average increase among those aged 75 or older.

A second analysis by Ms. Paradaens and her associates, reported in a separate poster, focused on 371 patients who underwent cardiac rehabilitation at Ghent University during January 2010 through May 2012 from among the 1,253 patients hospitalized during this period for an acute coronary syndrome event, cardiac surgery, or heart failure. In this pool of more than 1,000 patients who were potentially eligible to participate, only 30% actually enrolled in the rehabilitation program. The cardiac rehabilitation program again involved two to three sessions per week, with a goal for patients to complete 45 sessions within 5 months.

The sign-up rate for rehabilitation lagged even more among the 428 patients from the larger group whose index hospitalization had been for heart failure, with 37 of the acute heart failure patients (9%) actually engaging in rehabilitation. Rehabilitation participation was highest, a 56% rate, among the 358 patients who had been hospitalized for cardiac surgery, with a 28% uptake rate among 467 patients who had an ACS event.

Despite the low, 9% uptake of cardiac rehabilitation in heart failure patients, their benefit from participation

closely tracked the benefit seen in surgery and ACS patients. Improvement in peak exercise capacity over baseline at the end of rehabilitation averaged 19% in the heart failure patients, 17% in the ACS patients, and



Patients aged 75 and older improved capacity 16%, Sofie Paradaens reported.

24% in the surgery patients, differences that were not statistically significant, reported Ms. Paradaens. All three subgroups also had similar average improvements in their 6-minute walk distance, which rose by an average of 21% in the heart failure patients and by averages of 27% and 28% in the other two subgroups.

Ms. Paradaens and her associates said they had no relevant financial disclosures.

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VIEW ON THE NEWS

Dr. Jun Chiong, FCCP, comments: Cardiac rehabilitation is undoubtedly an essential component of the contemporary treatment of patients with coronary disease and heart failure.

Exercise training has the potential to act as a catalyst for promoting other aspects of rehabilitation, including risk factor modification through therapeutic lifestyle changes and optimization of psychosocial support. Similarly, among patients who are elderly, such outcome measures may include the achievement of functional independence, the prevention of premature disability, and a reduction in the need for custodial care.

Despite limited data, older patients have shown improvement in their exercise tolerance comparable to that of younger patients participating in equivalent exercise programs. In addition, the safety of exercise within cardiac rehabilitation programs is well accepted and established.



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CHEST Physician

THE NEWSPAPER OF THE AMERICAN COLLEGE OF CHEST PHYSICIANS

Oxygen debt is linchpin in multiple organ dysfunction

The level of perioperative tissue debt has a direct relationship on postoperative morbidity, mortality.

BY DOUG BRUNK

IMNG Medical News

SAN FRANCISCO – In the opinion of Dr. Larry H. Hollier, multiple organ dysfunction syndrome is a condition “underappreciated” by many of today’s clinicians, as optimal ways to treat it remain elusive.

At the Society for Vascular Surgery Annual Meeting, Dr. Hollier, professor of surgery and chancellor of the Louisiana State University Health Sciences Center, New Orleans, defined multiple organ dysfunction syndrome (MODS) as altered organ functions in an acutely ill patient requiring intervention to achieve homeostasis.

“That’s a pretty broad definition, but it’s one of the most common causes of death in surgical intensive care units,” he said. “Numerous precipitating factors classically described in multiple organ dysfunction syndrome include sepsis, trauma, cardiac arrest, visceral ischemia, burns, pancreatitis, shock, and major surgery with postoperative instability.”

The pathophysiology of MODS “is fairly straightforward,” he continued. “Some event results in ischemia and tissue hypoxia. Reperfusion occurs with the activation of cytokines, and an exaggerated inflammatory response generates oxygen-free radicals, tissue damage, and then organ dysfunction.” Dr. Hollier discussed these issues as the invited speaker for the prestigious John Homans Lectureship of the SVS.

The major underlying issue in MODS stems from uncorrected oxygen debt in tissues. In fact, the level of perioperative tissue debt has a direct relationship on postoperative morbidity and mortality. According to Dr. Hollier, the predicted outcome by acutely accumulated oxygen debt in the first 4 hours post injury works like this: 8 L/m² leads to a severe flulike syndrome (mild systemic inflammatory response syndrome); 26 L/m² leads to multiple organ dysfunction syndrome; and 33 L/m² or more leads to death. “The uncorrected oxygen debt in tissues that is initiated is not the end

of it,” he said. “There’s an accumulating oxygen debt that amasses to keep biomass viable during low oxygen delivery. After resuscitation, there’s increased oxygen required above the basal rate, because explosive oxygen needs occur in order to fuel the inflammation of reperfusion injury.”

Conventional therapies for MODS include volume resuscitation,

Multiple experimental therapies have been used, including steroids, IL-1 receptor antagonists, anti-TNF antibodies, antioxidants, inhibition of nitric oxide, and oxygen manipulation.

ionotropic agents to improve cardiac performance and increase oxygen delivery, and ventilator support to improve oxygen input. Multiple experimental therapies have also been used, including steroids, antiendotoxin monoclonal antibodies, IL-1 receptor antagonists, anti-TNF antibodies, antioxidants, inhibition of nitric oxide, and oxygen manipulation in the form of extracorporeal support and perflu-

orocarbons. “While there is some research experience, in the clinical arena, there has universally not been a treatment that reverses the multiple organ dysfunction syndrome,” he said. “Early diagnosis and prompt treatment of organ hypoperfusion and hypoxia are of utmost importance. The major goal is to increase oxygen delivery as soon as possible.”

Dr. Hollier said that he had no relevant financial disclosures to make.

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Current but not past smokers at postoperative risk

Surgery teams should take advantage of their 'teachable environment' to help patients quit.

BY MARY ANN MOON
IMNG Medical News

Current smoking is associated with an increased risk of mortality and other adverse outcomes following major surgery, but past smoking is not, according to a report in JAMA Surgery.

Current smoking correlates with these adverse outcomes even in patients who don't have obvious smoking-related disease such as cardiovascular disease, chronic pulmonary disorders, or cancer, which suggests that smoking may exert its deleterious effects through acute or subclinical chronic vascular and respiratory pathologic mechanisms, said Dr. Khaled M. Musallam of the American University of Beirut (Lebanon) Medical Center and his associates.

Since smoking cessation has clear benefits on morbidity and mortality in the surgical setting, "surgical teams should be more involved in the ongoing efforts to optimize measures for smoking control," they wrote.

"Surgery provides a teachable environment for smoking cessation. Unlike the long-term consequences of smoking, the acute consequences of

smoking on patients' postoperative outcomes can provide a strong motive for quitting," the investigators said.

Dr. Musallam and his colleagues examined the effect of smoking on surgical outcomes using data from the American College of Surgeons National Surgical Quality Improvement Program (NSQIP), which includes a registry that provides feedback to participating hospitals regarding 30-day risk-adjusted surgical morbidity and mortality.

For this study, they analyzed data on 607,558 patients undergoing major surgery at more than 200 participating hospitals during a 2-year period in the United States, Canada, Lebanon, and the United Arab Emirates. The mean age of the patients was 56 years (range, 16-90 years); 43% were men and 57% were women.

A total of 125,192 patients (21%) were current smokers and 78,763 (13%) were past smokers who had quit at least 1 year before surgery. The remaining patients had never smoked.

Only current smokers showed an increased likelihood of 30-day mor-

tality. They also were at greater risk for adverse arterial events such as MI or stroke, as well as for adverse respiratory events such as pneumonia, need for intubation, and need for a ventilator, within 30 days of surgery, the investigators said (JAMA Surg. 2013 June 19 [doi:10.1001/jama-surg.2013.2360]).

The higher risk of these adverse outcomes occurred with smokers across all age groups but was particularly notable among those older than age 40 years. It was seen in both sexes, among those undergoing inpatient as well as outpatient procedures, in patients who had general as well as other types of anesthesia, across a variety of surgical subspecialties, and in both elective and emergency surgery cases.

The association between current smoking and adverse outcomes also remained robust in a sensitivity analysis, Dr. Musallam and his associates said.

There was a dose-response effect in an analysis of patients' smoking history, with the likelihood of adverse arterial and respiratory events increasing in tandem with increasing pack-years of smoking, but even current "light" smokers who had fewer than 10 pack-years of smoking history were at increased risk for postoperative mortality and morbidity.

"These findings encourage ongoing efforts to implement smoking cessation programs," Dr. Musallam and his associates said.

"Early intervention in heavy smokers is warranted, especially because the effect of smoking on postoperative arterial and respiratory morbidity seems to be dose dependent. However, because smokers with a cigarette smoking history of less than 10 pack-years are also at risk of postoperative death, recent and light smokers should also be targeted," they suggested.

Dr. Musallam and his associates reported no financial conflicts of interest.

VIEW ON THE NEWS

Dr. Marcos I. Restrepo, FCCP, comments: This is another message

showing the deleterious effects of smoking, this time on patients undergoing major surgery. The need for major surgery is the perfect moment to stop smoking. Please do not miss this opportunity!



Inhaled adrenaline akin to saline for acute bronchiolitis

BY MARY ANN MOON
IMNG Medical News

Inhaled racemic adrenaline is no more effective than inhaled saline for infants hospitalized with acute bronchiolitis, a study has shown.

In the multicenter, double-blind randomized trial involving 404 infants in Norway, hospital length of stay was no shorter for patients who received inhaled adrenaline than for those who received inhaled saline. The need for nasogastric-tube feeding, supplemental oxygen, or ventilatory support also was no different between the two groups, said Dr. Havard Ove Skjervén of Oslo University Hospital and his associates.

The findings were published in the New England Journal of Medicine.

Adrenaline inhalation, which reduces mucosal swelling, is used frequently for acute bronchiolitis in the outpatient setting, chiefly because it has been shown to improve symptoms and prevent the need for hospitalization. "Among inpatients, however, adrenaline has not been found to reduce the length of hospital stay," the investigators noted.

They studied the issue in babies aged younger than 1 year (mean age, 4 months) who were ad-

mitted to the pediatric departments of eight hospitals during a 1-year period. A total of 102 infants were randomly assigned to receive inhaled adrenaline on demand, 101 to receive inhaled adrenaline on a fixed schedule, 98 to receive saline on demand, and 103 to receive saline on a fixed schedule.

The primary outcome was length of hospital stay. The mean length of stay for the entire study population was 80 hours.

There was no significant difference in length of hospital stay between the infants treated with adrenaline (78.7 hours) and those treated with saline (81.8 hours).

There also were no significant between-group differences in the need for feeding using a nasogastric tube, supplemental oxygen, or ventilatory support, the researchers said (N. Engl. J. Med. 2013 June 12 [doi:10.1056/NEHMOa1301839]).

In addition, the infants were scored on a measure of clinical appearance, which took into account their general condition, skin color, findings on auscultation, respiratory rate, and chest retractions. These scores also did not differ significantly between infants given their first dose of inhaled adrenaline and those given their first dose of inhaled saline.

The two study groups also were similar in the number of children who discontinued the study medication. No serious adverse events were reported.

These findings did not change in a subgroup analysis that categorized the infants by age (younger vs. older than 3 months). They also remained robust regardless of whether the patients had a history of atopic eczema or wheezing, or a family history of atopy.

However, it was notable that among the youngest patients (less than 3 months of age), length of hospital stay was significantly shorter and secondary outcomes were better for those who received either adrenaline or saline inhalation on demand than for those who received either drug on a fixed schedule. Because the on-demand groups received a mean of 5 (30%) fewer inhalations than the fixed-schedule groups, this suggests that "minimal handling" – allowing infants to sleep, with minimal interruptions – is the preferred approach for this age group, Dr. Skjervén and his associates said.

This study was supported by Medicines for Children, a publicly funded group administered by Haukeland University Hospital. Dr. Skjervén reported no relevant financial disclosures; his associates reported ties to numerous industry sources.

Device cuts DVT risk, saves stroke patients' lives

Compression sleeve led to significantly fewer proximal events; ensuring eligible patient access is next step.

BY SARA FREEMAN
IMNG Medical News

LONDON – Intermittent pneumatic compression reduced the absolute risk of proximal deep vein thrombosis in patients who had suffered a stroke and were immobile by 3.6% in a large, randomized trial published recently.

The incidence of proximal DVT at 30 days in the CLOTS 3 study was 8.5% with intermittent pneumatic compression (IPC) and 12.1% with routine poststroke care alone ($P = .001$). The adjusted odds ratio was 0.65. There was also a 14% re-



Dr. Martin Dennis treats stroke patient Yvette Henderson with an intermittent pneumatic compression.

duction in the risk of death seen at 6 months favoring IPC use over routine care alone ($P = .042$). This was a surprising finding, said principal investigator Dr. Martin Dennis of the University of Edinburgh's clinical neurosciences division and Western General Hospital in Edinburgh. He is a professor of stroke medicine.

Importantly, IPC appears to be effective across a variety of prespecified subgroups, including both ischemic and hemorrhagic stroke.

Findings will change practice

The findings, which were published online in *The Lancet* (2013 May 31 [doi: 10.1016/S0140-6736(13)61050-8]) to coincide with their presentation at the annual European Stroke Conference, are practice changing

and suggest that national stroke guidelines need to be updated.

"This study is a major breakthrough, showing how a simple and safe treatment can save lives," Dr. Tony Rudd, a consultant stroke physician at Guy's and St. Thomas' NHS Foundation Trust, London, said in a statement issued by the University of Edinburgh.

"The challenge now will be to ensure that all patients who might benefit are offered treatment," added Dr. Rudd, who chairs the Royal College of Physicians' Intercollegiate Stroke Working Party. "It is one of the most important research studies to emerge in the field of stroke in recent years," he noted.

Dr. Christine Roffe, consultant in stroke medicine and professor of medicine at Keele University in Stoke-on-Trent, England, also praised the study's results. "That something as simple as a compressive sleeve saves lives after stroke is fascinating," she said in an interview at the conference. Dr. Roffe was not involved in the study.

The CLOTS 3 study

CLOTS 3 follows on from two other trials performed by the CLOTS (Clots in Legs or Stockings After Stroke) Trials Collaboration, in which compression stockings were examined as a possible means of preventing thrombotic complications in patients who had suffered a stroke. Results of CLOTS 1 (*Lancet* 2009;373:1958-65) and CLOTS 2 were negative, however, and no benefit of compression stockings was seen in stroke patients.

Between December 2008 and September 2012, a total of 2,876 patients were enrolled in CLOTS 3. For inclusion, patients had to be immobile and randomized within 0-3 days of having had a stroke. Immobility was defined as being unable to walk to the bathroom without the help of another person.

Patients were randomized to receive either routine poststroke care alone or with additional IPC delivered by Covidien's Kendall SCD Express Sequential Compression System. The latter involved wearing thigh-high, inflatable sleeves continuously for up to 30 days, during which time the device automatically provided IPC depending on the position of the patient. The mean and median

durations of wear were 12.5 days and 9.0 days, respectively.

DVT was assessed using duplex ultrasound at 7-10 days and again at 25-30 days if possible. Both patient groups wore compression sleeves to ensure that the ultrasound technicians remained blinded to the treatment group.

Follow-up was at 6 months via postal questionnaires sent to patients' primary care physicians asking about vital status and the occurrence of venous thromboembolism since hospital discharge. Patients were also sent a postal questionnaire and telephoned if they did not respond.

Risk reduction

The effect on proximal DVT at 30 days was the primary outcome measure, but IPC also reduced the incidence of symptomatic DVT (4.6% vs. 6.3%; $P = .0045$) and any DVT (16.2% vs. 21.1%; $P = .001$) versus routine care. There was no significant difference in the incidence of pulmonary embolism between study arms (2.0% vs. 2.4%, respectively, $P = .453$).

In terms of safety, there was no difference between the treatment groups in the number of falls with injury or fractures as a result of constantly wearing the compression sleeves. There was a significant difference in skin ulcers (3.1% with IPC vs. 1.4% without, $P = .002$), but close inspection of the data suggested that only 10 (0.7%) cases were due to IPC.

"During the study, [the manufacturers of the IPC device] brought out a new comfort sleeve," Dr. Dennis noted in an interview.

"Normally these sleeves were being used for short periods in surgical patients, but we were using them for longer periods, so they brought out a softer sleeve," he observed. Anecdotally, he conceded that some people found the sleeves uncomfortable, too hot, or the system "noisy" to use.

The bottom line is that "intermittent pneumatic compression in people who are immobile with stroke reduces the risk of deep vein thrombosis," Dr. Dennis said.

He emphasized that "IPC is feasible in stroke patients, and it is relatively safe. It is an effective means of reducing venous thromboembolism after stroke, with a number needed to treat of about 28 for proximal DVT."

Intriguingly, it may also improve

overall survival, "although we weren't expecting to see that effect," Dr. Dennis said. The number needed to treat to prevent one death in 30 days was 43.

Dr. Dennis, Dr. Rudd, and Dr. Roffe had no relevant disclosures. The University of Edinburgh and NHS Lothian sponsored the study with funding from the Chief Scientist Office of the Scottish Government, the National Institute of Health Research Health Technology Assessment Programme, and the Scottish Stroke Research Network. Covidien provided the equipment used in the study free of charge.

VIEW ON THE NEWS

Dr. Robert Pendleton, FACP,

comments: Venous thromboembolism is a common cause of hospital-related morbidity. Anticoagulants (e.g., heparin, low-molecular-weight heparin [LMWH]) reduce VTE with acceptable safety. Stroke patients have a high risk of VTE, but also a heightened bleeding risk in the setting of anticoagulants. Mechanical devices (elastic stockings, sequential compression devices) are attractive alternatives, but efficacy is unproven in many settings.

Unlike previous trials that demonstrated a lack of efficacy of elastic stockings, the CLOTS 3 study provides convincing evidence that sequential compression devices (SCDs) reduce VTE and decrease mortality in patients with a stroke. Although encouraging, VTE event rates remained high, 8.5%, in contrast to VTE rates of 4.8% in a prior study of enoxaparin in stroke patients.

Together, these findings support recommendations by the American College of Chest Physicians: In patients with acute ischemic stroke and restricted mobility, use prophylactic-dose subcutaneous heparin or LMWH or intermittent SCDs as opposed to no prophylaxis.

Dr. Pendleton is chief medical quality officer for University of Utah Health Care, Salt Lake City.



Antiemetic cuts pneumonia in intubated stroke patients

BY SARA FREEMAN
IMNG Medical News

LONDON – Metoclopramide significantly reduced the incidence of pneumonia in intubated stroke patients and was associated with improved mortality in a single-center, randomized controlled study.

A total of 34 of 60 (57%) patients in the trial developed pneumonia, of whom the majority (87%) received a placebo, while only 8 (27%) cases occurred in patients who received the antiemetic therapy.

A third of the cohort died by 30 days, but of these 20 deaths, 12 occurred in the placebo group versus 8 in the metoclopramide arm.

Neurological improvement also was seen in the patients given metoclopramide, Dr. Anushka Warusevitane of University Hospital of North Staffordshire in Stoke-on-Trent, England, reported at the annual European Stroke Conference.

For the whole group, National Institutes of Health Stroke Scale (NIHSS) scores were 19.3 at baseline, indicating moderate to severe stroke, 16.8 at 1 week, 17.4 at 2 weeks, and 19.6 at 3 weeks post stroke.

In the trial, adult patients admitted to the acute stroke unit within 7 days of having a stroke and who needed a nasogastric tube fitted for more than 24 hours were randomized to receive metoclopramide 10 mg three times a day or the same volume of a similar-looking placebo for a maximum of 3 weeks. All patients received standard stroke care.

The average age of the 60 patients finally recruited was 78 years, 63% were female, and 93% had cerebral infarcts.

Pneumonia was diagnosed according to four criteria outlined by the British Thoracic Society: acute lower respiratory tract infection symptoms; new focal chest signs; fever (more than 38° C), chills and rigors, elevated white cell count, or increased inflammatory markers; and new radiological shadowing.

Dr. Warusevitane reported that all of the episodes of pneumonia occurred within 10 days of the initiation of nasogastric feeds. The average time for pneumonia to develop was significantly longer in the metoclopramide group (4 days versus 2 days for placebo). Significantly shorter periods of antibiotic use were noted in the active versus placebo arm, at a mean of 2 days and 8 days, respectively.

Only 1 patient given metoclo-

pramide had an episode of aspiration, which was witnessed by a health care professional, compared with 14 patients given placebo. There was evidence that once the nasogastric tube was removed, the actively

treated patients had a better swallowing response.

“I’m convinced enough to change practice locally,” senior study author Dr. Christine Roffe said in an interview. Dr. Roffe, professor of medi-

cine at Keele University, England, conceded that a single-center study of just 60 patients might not convince the wider stroke community.

Dr. Warusevitane and Dr. Roffe reported having no disclosures.

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CHEST *Physician*

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Wedge resection in NSCLC: Is 15 mm the magic margin?

BY PATRICE WENDLING

IMNG Medical News

MINNEAPOLIS – Increasing the surgical margin length up to 15 mm during wedge resection of small lung cancer tumors significantly lowered the risk of local recurrence among 474 consecutive patients.

No additional benefit was observed, however, beyond 15 mm, said Dr. Kamran Mohiuddin, a surgical research fellow at Brigham and Women's Hospital, Boston.

Compared with a margin length of 5 mm, the adjusted risk of local recurrence was estimated to be 45% lower with a margin length of 10 mm (hazard ratio, 0.55), 59% lower with a 15-mm margin (HR, 0.41), and 54% lower with a 20-mm margin (HR, 0.46).

"The downward trend flattens out, indicating diminished benefit of increasing the margin length," he said at the annual meeting of the American Association for Thoracic Surgery.

Currently, the data are unclear regarding the optimal margin length for wedge resection of small non-small cell lung cancer (NSCLC) tumors of less than 2 cm. Wedge re-



DR. MOHIUDDIN

sections are associated with margins less than 1 cm and a high risk for locoregional recurrence (Ann. Surg. Oncol. 2007;14:2400-5), with a multicenter, prospective study suggesting that the optimal margin length should be larger than the maximum tumor diameter (Ann. Thorac. Surg. 2004;77:415-20).

When asked during a discussion of the analysis whether a more aggressive resection or segmentectomy would be performed if margins are found in the operating room to be inadequate based on the current results, senior author Dr. Scott J. Swanson, director of minimally invasive thoracic surgery at the hospital, said they are taking the results forward into practice, but that it's unclear whether 15 mm is the optimal number to target.

"Is 15 mm the correct margin? I am not sure we know the answer in all cases, but it is a useful number to keep in the surgeon's head when we are doing resections for tumors that are 2 cm or less," he said in an interview. "A 15-mm margin seems to be a better target to aim for than margin length to tumor diameter ratio of greater than 1, as suggested by other investigators."

The current analysis included data from all patients, aged 21-85 years, who underwent wedge resection for NSCLC 2 cm or less at their institution between January 2001 and August 2011. Margin length, defined as the distance from the tumor to the

VIEW ON THE NEWS

Dr. Lary Robinson, FCCP, comments: The researchers found that the greater the closest stapled margin (termed the margin length) the lower the recurrence rate up to a 15-mm margin length, where the recurrence rate plateaued. That is, doing a wedge resection with a margin length greater than 15 mm for a small peripheral tumor did not appear to further decrease the local recurrence rate. Nevertheless, the overall local recurrence rate in this entire cohort of 474 patients was



16.8% at 3 years.

Still, the standard of care for lung cancer resection for stage IA NSCLC is a lobectomy in physiologically fit patients. However, when a lesser resection is desired because of limited lung function or there are multiple small tumors in more than one lobe and a sublobar resection is planned, this analysis may give the surgeon some guidance in planning the lesser resection and interpreting the pathology results.

closest stapled resection margin, was 0.1-0.5 cm in 36%, 0.6-1.0 cm in 25.5%, 1.1-2.0 cm in 28.5%, and greater than 2 cm in 10%.

The mean tumor size was 1.33 cm, the location of the tumor was the right upper lobe in the majority (36%), and video-assisted thoracic surgery (VATS) was used in 57.5%. The patients' mean forced expiratory volume in 1 second (FEV₁) was 79.8%, and the mean age was 68.5 years.

Perioperative death occurred in 1 patient and at least one major complication in 41 patients, Dr. Mohiuddin said.

The local recurrence rate was 5.8% at 1 year, 11.3% at 2 years, and 16.8% at 3 years. Median follow-up

was 3.9 years.

In multivariate regression analysis, increased margin length was significantly associated with a lower risk of local recurrence, with evidence of diminished additional benefit beyond a length of 15 mm ($P = .031$), he said. The analysis adjusted for FEV₁, chronic obstructive pulmonary disease, smoking, diabetes, tumor size, tumor lobe location, location within the hemothorax, surgeon, whether VATS or open surgery was used, and whether or not nodes were sampled.

Dr. Mohiuddin and his coauthors reported having no financial disclosures.

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ACP restates 140- to 200-mg/dL blood glucose target

BY M. ALEXANDER OTTO

IMNG Medical News

Blood glucose levels should be targeted to 140-200 mg/dL in surgical or medical ICU patients on insulin therapy, according to advice the American College of Physicians published in the American Journal of Medical Quality.

Also, "clinicians should avoid targets less than ... 140 mg/dL because harms are likely to increase with lower blood glucose targets," the group said (Am. J. Med. Qual. 2013 [doi:10.1177/1062860613489339]).

The advice isn't new, but instead a restatement of ACP's 2011 inpatient glycemic control guidelines reissued as part of its "Best Practice Advice" campaign, said Paul G. Shekelle, Ph.D., senior author of both the advice paper and guidelines (Ann. Intern. Med. 2011;154:260-7).

"This is based on the prior guidelines, so there's nothing new here in that sense. The Best Practice Advice series sometimes runs in parallel to the guidelines, sometimes it is something completely

different than any ACP guidelines, and sometimes, like this case, it runs asynchronous to the guidelines. Ideally, these will be more synchronous in the future," Dr. Shekelle, director of the RAND Corporation's Southern California Evidence-Based Practice Center, said in an interview.

ACP's advice is largely in keeping with glucose control recommendations from other groups, which have tended toward liberalization in recent years amid evidence that aggressive, euglycemic control in hospitalized patients, even if they have diabetes, doesn't improve outcomes and carries too high a risk of hypoglycemia and its attendant problems.

"Nobody is advocating tight glycemic control anymore in the hospital. It isn't necessary and may be harmful," said Dr. Etie S. Moghissi, the lead author on a 2009 inpatient glycemic control consensus statement issued by the American Association of Clinical Endocrinologists and American Diabetes Association (Diabetes Care 2009;32:1119-31).

The consensus statement recommended an up-

per limit of 180 mg/dL based on the pivotal NICE-SUGAR study, instead of 200 mg/dL, which Dr. Shekelle said ACP chose because it was the upper target limit in several of the additional studies upon which the group based its 2011 guidelines (N. Engl. J. Med. 2009;360:1283-97).

But Dr. Moghissi, who is with the department of medicine at the University of California, Los Angeles, said she's concerned that 200 mg/dL might be too high.

"We know that when we set targets, people do not achieve them. So when we set a higher target, most of the time people go above that. The concern is that a target of 200 mg/dL "may be perceived [as meaning that] a little bit over 200 mg/dL is okay," but "above 200 mg/dL, usually there are issues with increased risk of infection, poor wound healing, volume depletion," and other problems, she said in an interview.

Dr. Shekelle and Dr. Moghissi said they have no relevant disclosures.

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Empiric echinocandin deemed best for candidemia

BY M. ALEXANDER OTTO
IMNG Medical News

LAS VEGAS – An echinocandin should be used for empiric therapy in critically ill candidemia patients awaiting culture results, according to investigators from Wayne State University in Detroit.

The reason is that *Candida glabrata* is on the rise in the critically ill, and it's often resistant to fluconazole, the usual empiric choice, said Dr. Lisa Flynn, a vascular surgeon in the department of surgery at the university.

Dr. Flynn and her colleagues came to their conclusion after reviewing outcomes in 91 critically ill candidemia patients. Just 40% (36) had the historic cause of candidemia, *C. albicans*, which remains generally susceptible to fluconazole; 25% (23) had *C. glabrata*; and the rest had *C. parapsilosis* or other species.

Before those results were known, 53% (48) of patients were treated empirically with fluconazole and 36% (33), with the echinocandin micafungin. Most of the others received no treatment.

Seventy percent (16) of *C. glabrata* patients got fluconazole, the highest

rate in the study of inappropriate initial antifungal therapy; probably not coincidentally, 56% (13) of the *C. glabrata* patients died; the mortality rate in patients with other candida species was 32% (22). On univariate analysis, mortality increased from 18% to 37% if *C. glabrata* was cultured.

"When we looked at *glabrata* versus all other candida species, we found significant increases in in-hospital mortality" that corresponded to a greater likelihood of inappropriate initial treatment, she said at the annual meeting of the Surgical Infection Society.

For that reason, "we are proposing that initial empiric antifungal therapy start with an echinocandin in the critically ill patient and then de-escalate to fluconazole if [indicated by] culture data," she said.

It's sound advice to use empiric antifungal therapy starting with an echinocandin in the critically ill patient and then de-escalating to fluconazole if indicated by culture data, so long as "your incidence of *Candida glabrata* is high," session moderator Dr. Addison May said after the presentation.

"It really depends on your hospital's rate, and how frequently it's [isolated]. It's important to understand what you

need to empirically treat with," but also important to use newer agents like micafungin judiciously, to prevent resistance, said Dr. May, professor of surgery and anesthesiology at Vanderbilt University in Nashville, Tenn.

C. glabrata patients were more likely than others to be over 60 years old; they had longer hospital and ICU stays, as well.

The mean APACHE II (Acute Physiology and Chronic Health Evaluation II) score in the study was 25, and the mean age was 57 years; 54% (49) of patients were men, and 68% (62) were

black. In the previous month, almost half had surgery and a quarter had been on total parenteral nutrition.

Central lines were the source of infection in 84% (76).

On multivariate analysis, inappropriate initial antifungal treatment, vasopressor therapy, mechanical ventilation, and end-stage renal disease were all significant risk factors for death.

Dr. May and Dr. Flynn said they had no relevant financial disclosures.

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VIEW ON THE NEWS

Dr. Steven Q. Simpson, FCCP,

comments: This article underscores the need for understanding our local fungal isolates and their resistance profiles, and it doesn't even mention the additional problem of fluconazole resistance among *C. albicans* isolates. The question that is more difficult to answer is that of when, in the course of changing



resistance patterns, it is important to change empiric therapy. We will face this issue more and more in the future, since anti-infective development is slow-paced and almost nonexistent, while resistance development seemingly proceeds at a gallop. How do we balance the risk for an individual patient with the ultimate risk to all patients?



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9:15 AM – 10:30 AM
Keynote Speaker:
Chris Draft
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PALLIATIVELY SPEAKING: Readmission – Symptom or problem?

BY LEIGH FREDHOLM, M.D., AND STEPHEN J. BEKANICH, M.D.

IMNG Medical News

Among the myriad efforts at performance improvement in our hospital system, none loom larger than those aimed at preventing readmissions.

While clinicians have long known that patients' outcomes suffer when they are readmitted to the acute care hospital, now hospital outcomes will also suffer – financial-

ly, by up to 2% of Medicare billings for FY 2014, with greater penalties in future years.

Our system expects to lose \$575,000 for FY 2013, when the penalty is a more modest 1% of Medicare billings. Efforts to prevent readmissions to date have focused primarily on finding and eliminating process gaps: Have we adequately educated the patient and family about

medications, treatments, follow-up appointments? Are there transportation challenges? Can the patient afford and obtain medications? National efforts have addressed the most common gaps. These efforts are very effective for the patient whose illness trajectory is one of slow and steady improvement.

As patients enter the final phase of a serious illness, the trajectory is progressive decline, despite available treatments. Trajectory of decline is characterized by functional de-

cline, loss of lean body mass, and the need for frequent medical care (hospitalization, ED and physician visits). These patients have multiple transitions between and among health care settings. Recent analysis of data from the Centers for Medicare and Medicaid Services was discouraging: Though hospice at time of death doubled between 2000 and 2009, nearly a third of those patients were

in hospice 3 or fewer days. Forty percent of those short-stay patients were discharged to hospice from an ICU. Fourteen percent of Medicare decedents in 2009 had at least one transition of care in the last 3 days of life (JAMA 309:470-77).

On the palliative care service, we encounter a group of patients who are frequently readmitted, not because of process gaps, but because they are too ill to live well outside of the hospital without significant assistance. For these patients, the readmission is a symptom, not the problem.

The problem is that the patient is dying. How can we better manage the transition away from acute care for the patient whose death is expected? Often these patients are readmitted because we have not provided an alternative to hospital admission for the next crisis. Medicare skilled nursing facilities, and long-term acute care and rehabilitation hospitals, are designed to care for patients whose conditions are improving, and as a result, they rapidly transfer declining patients back to the acute care hospital.

Hospice, as an interdisciplinary 24-hour model of care, is uniquely positioned to treat symptoms and assist the patient and family to cope with distress and grief. Hospices are required to provide respite to caregivers as well as options for inpatient care when the patient's symptoms cannot be reasonably managed in another setting. Hospice admission within 30 days of death significantly reduces the likelihood of 30-day readmission, subsequent ICU admission, and death in the hospital (Health Aff. 2013;32:552-61). Greater reduction in the likelihood of these outcomes is seen with hospice admission at least 53 days before death. Ironically, hospice patients have demonstrated longer life expectancy than their disease-matched counterparts (J. Pain Symptom Manage. 2007;33:238-46).

Patients with serious, progressive illness need concrete information about the natural history of the illness, its expected course and prognosis, and the potential impact of proposed treatments on morbidity as well as mortality. Understanding what is expected in the illness often alters the choices patients make about treatment and postacute care. After disease education, a patient and family can select goals of care and treatment options that align with their preferences. When asked, most laypersons prefer to die at home, comfortably, with their family. For these patients, the

question is not "Do you want to die?" but "How do you want to die?" These conversations are difficult for all involved (physician, patient, family), but allow patients to make truly informed

The problem is that the patient is dying. How can we better manage the transition away from acute care for the patient whose death is expected?

decisions about their care, and to decide what is most important as death approaches.

Lacking complete information, patients are often subjected to a merry-go-round of transfers between the acute and postacute environments, with increased caregiver stress. Attention to goals of care results in fewer readmissions, higher satisfaction, and better outcomes for patients and health care organizations.

Palliative care teams can provide consultative assistance with these conversations, and may be available to provide additional training to health care providers as well. If your institution does not have a palliative care team, look to a board-certified palliative medicine clinician in your community (often the hospice medical director) for consultation and guidance.

Dr. Fredholm and Dr. Bekanich are codirectors of Seton Health Palliative Care, part of the University of Texas Southwestern Residency Programs in Austin.



DR. FREDHOLM



DR. BEKANICH

BEYOND OUR WALLS.

A campaign for the American College of Chest Physicians

Advancing the Future of Chest Medicine

Your financial support is needed to help the ACCP achieve its \$5 million goal and to advance lung and heart health for patients everywhere.

In early 2014, the ACCP will move into a dynamic new headquarters in Glenview, Illinois, propelling the College to a new model of education delivery that is hands-on, in-depth, and flexible. With a year-round center for immersive training and innovation, as well as on-demand access to tools for health-care providers, the ACCP will have a platform to advance chest medicine and the wellness of your patients.

The 48,500 square foot Silver LEED-certified headquarters will be housed on ample, verdant grounds that create a sense of calm retreat; facilitate exchange and collaboration; and, most importantly, reflect the ACCP commitment to environmental sustainability—and cleaner air and healthier lungs.

With the help of members, friends, and supporters, the ACCP can take the next great leap in advancing chest medicine and wellness—one whose effects will be felt well beyond its walls. Philanthropy will enable the ACCP to realize this goal and advance lung and heart health for patients everywhere.

Contribute to the Campaign Today—opportunities to contribute are available at all levels. Donors of \$25,000 or more have a variety of naming options, ranging from conference rooms to simulation suites to the entire campus. Visit beyondourwalls.chestnet.org to take a virtual tour of the new headquarters, view the campaign video, or learn about the benefits of giving.

Buy a Brick—cement your place in ACCP history. Purchase a brick for \$1,000 and ensure that your generosity will be recognized in perpetuity. Bricks are an ideal way to pay tribute to a colleague, to memorialize a friend, or to simply show your support to improving lung and heart health. There are a limited number of bricks available, so secure your paver today.

Learn more about the campaign by visiting beyondourwalls.chestnet.org or call (847) 498-8130.



BEYOND OUR WALLS.



VIEW ON THE NEWS

Dr. Paul A. Selecky, FCCP, comments: Our palliative care colleagues make an interesting point on the growing concerns about preventing readmissions for flares of chronic disease. Some of our patients might be eligible for hospice care, an underutilized resource to treat a long life of suffering. Palliative care teams are uniquely qualified by providing a multidisciplinary approach to these patients, ideally done before the need for hospitalization.



FROM THE PRESIDENT: CHEST World Congress 2014 – New, innovative, forward-thinking, Madrid ...

BY DR. DARCY D. MARCINIUK, FCCP

I want to share with you the latest news about the CHEST World Congress (CWC) 2014 to be held in Madrid on March 21-24, 2014. This educational conference is definitely creating some excitement. The preparations for CWC 2014 are proceeding rapidly with an enthusiastic commitment to assemble the best clinical educational offering possible.

Dr. Mark J. Rosen, FCCP, Director of Global Education and Strategic Development, and ACCP Past President (2006-2007), is keeping you well informed about the how the program is developed in this issue of *CHEST Physician* (see page 18).

The Scientific Program Committee is composed of more than 25 international experts and is led by co-chairs Drs. Richard Irwin and Joan Soriano. I confirm that they are doing an extraordinary job. It is truly inspiring to see so many world leaders and experts work diligently, devoted to putting together the very best possible program for attendees from around the world.

New heights ...

CWC 2014 isn't the first international conference held outside the United States or Canada by the ACCP. The list of venues is impressive: Rio De Janeiro 1952, Barcelona 1954, Colombia 1956, New Delhi 1958, Vienna 1960, Mexico City 1964, Copenhagen 1966, Lausanne 1970, and London 1974. ACCP meetings were held in Rome twice: the first in 1950, and again in 1977. The ACCP holding first-rate conferences around the world is nothing

new, but what is new is that CWC 2014 will reach new heights of educational excellence and be a truly unique and refreshing opportunity.

CWC 2014 builds on the proven expertise and commitment to clinical education of both the ACCP and SEPAR (Sociedad Española de Neumología y Cirugía Torácica – our colleagues from Spain). I just returned from the annual SEPAR Congress in Barcelona, a conference with a long and proud tradition. It was extremely well attended and was fortified with leading experts in areas covering the entire spectrum of our field. Quite simply, the goal of the ACCP-SEPAR partnership is to put together the very best educational conference possible. CWC 2014 will take the best from both the ACCP and SEPAR and achieve that goal by providing a new international platform for chest medicine that allows the genuine sharing of ideas and expertise with clinical colleagues from around the world.

Innovative ...

From the start, CWC 2014 is designed to be an international conference very different from traditional meetings. Innovative and varied educational methods and techniques will be used to create unique learning experiences for everyone. There will, of course, be lectures from world ex-



See you at CWC in Madrid, March 21-24, 2014!

perts and pro/con debates on controversial topics in clinical medicine, along with smaller sessions allowing you to get close to leading professors. But there will also be an abundance of lively interactive sessions, enabling you to actively participate in your learning throughout the conference. Be prepared for true high-fidelity, simulation-based clinical learning scenarios and immersive experiences. Look for advanced case- and problem-based sessions and small-group interactive discussions. And completely new to other international conferences, there will be a variety of self-study stations available throughout the venue, further complementing the entire CWC 2014 program.

Forward-thinking ...

At the direction of Drs. Irwin and Soriano, the vision for the Congress is to look forward and anticipate the future, and to prepare today's practicing clinician for tomorrow. The Scientific Programme Committee designed the scientific program accord-

ingly to ensure that you, the practicing clinician, are standing at the vanguard of clinical chest medicine, and improving what matters most - the very best care for your patients. You'll also share this experience with clinical colleagues from the United States, Canada, and countries around the world.

Madrid, Spain ...

I've visited Madrid and Spain a number of times, and each visit was better than the last. Spain is rich in tradition and culture, and the warmth and hospitality of the Spanish people will make you feel comfortable the moment you arrive. Madrid has so much to see and offer - the world-famous Prado museum, incredible architecture, flamenco dancing, mouth-watering cuisines (... I can never get enough paella!), and exceptional wines. Plenty of exceptional wines!

My wife Carla and son Jeff accompanied me on my trips to Barcelona and to Madrid, and we shared a wonderful experience, one that I recommend for you and your family.

Learn more about CHEST World Congress 2014 at chestnet.org/Education/CHEST-Meetings/CHEST-World-Congress-2014, and consider submitting an abstract or case report (CHEST World Congress Topic Submission: www.surveymonkey.com/s/CWC2014) to have another reason to attend the CWC 2014.

New, innovative, forward-thinking, Madrid – that is CWC 2014! All from your trusted source for the very best clinical education in pulmonary, critical care, and sleep medicine. Now you can see why CWC 2014 is creating so much excitement!

Recent honors for ACCP Presidents, current and past



DR. DARCY D. MARCINIUK

Founders Award

Dr. Darcy Marciniuk, FCCP, current ACCP President, was recently honored by the Canadian Lung Association, which presented him with its highest honor, the Founders Award. The presentation took place during the Respirology State of the Art Conference, in Saskatoon, Canada, on June 1, 2013.

The Founders Award honors individuals who have devoted themselves to the affairs of the Lung Association and to the cause of respiratory health. Dr. Marciniuk is a well-recognized and respected world leader in lung health

and a pioneer in implementing the concept of chronic disease management for COPD. "This award, which recognizes exemplary innovation or commitment toward lung health, is conferred once every 2 years, and we were pleased to celebrate and recognize Dr. Marciniuk," says Dr. Brian Graham, president and CEO of the Lung Association of Saskatchewan.



DR. RICHARD S. IRWIN

Pioneering Spirit Award

Dr. Richard S. Irwin, Master FCCP, *CHEST* Editor in Chief, and Past President of the ACCP, was recently presented

with one of the American Association of Critical-Care Nurses' highest national honors, the Pioneering Spirit Award, at the AACN's National Teaching Institute & Critical Care Exposition. The award was presented by two of his longstanding colleagues, Dorrie Fontaine, RN, PhD; and Kathleen McCauley, PhD, RN, ACNS-BC, both past presidents of AACN.

Dr. Irwin was honored for his pioneering and visionary advocacy of collaborative leadership and interdisciplinary practice between medicine and nursing. The Pioneering Spirit Award from the AACN is supported by GE Healthcare and recognizes significant contributions that influence high acuity and critical care nursing and relate to the association's mission, vision, and values.

Planning for CHEST World Congress 2014

BY DR. MARK J. ROSEN,
FCCP

Director, Global Education and Strategic
Development, American College of Chest
Physicians

A small group of physicians and staff representing the ACCP and SEPAR are working in the background to coordinate the planning and complex activities that produce a meeting of the scale of CHEST World Congress (CWC) 2014. To that end, an Executive Program Committee was appointed, in Barcelona, Spain, on June 13. The Committee was charged with assembling a program for the general sessions, using a process modeled after the annual CHEST meeting. As for CHEST, an open call for topics yielded over 200 submissions from around the world, and the Committee selected 62 of them for general sessions. An international array of outstanding faculty is featured. After his splendid

work chairing the Program Committee session for this year's CHEST meeting in Chicago, Dr. Jack Buckley, FCCP, agreed to take on moderating the CWC Program Committee.

The group set out to develop a program that offers international perspectives on the future of chest medicine presented by an expert international faculty. To achieve this, the Program Committee consists of participants representing not only the United States, Canada, and Spain, but also Latin America, Italy, Greece, India, and China. Most had no experience planning for CHEST, but under Dr. Buckley's guidance, they put together a schedule for CWC that spans 3 days, offers international "star" faculty to cover a wide menu of topics, and is constructed carefully to avoid similar topics competing for the same time period.

As leaders in chest medicine themselves, the Committee members were also not shy about putting forward

strong opinions and ideas. Dr. Buckley skillfully kept the group on task, and at the end of the day, we had a very strong program.

The Call for Abstracts and Case Reports is underway until August 12. The process of submission and selection is also following the CHEST model, and we urge you to

take the opportunity to participate. All of the information about the Congress, including the link to submit topics and case reports, is found at the official website: chestworldcongress2014.org.

We look forward to your contribution to the Congress and to seeing you in Madrid next March.



The Executive Program Committee for CHEST World Congress 2014.

CHEST 2013: Come for just 1 day, or make a whole weekend of it

If you'd like to attend CHEST 2013 but have trouble scheduling time away from your practice, consider the 1-day registration.

Register for any given day, Sunday through Thursday. Or, attend for the weekend by registering for a postgraduate



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course on Saturday and 1 day on Sunday. If you come for the weekend, consider bringing your family. There's so much to do for everyone in Chicago.

Postgraduate Courses

Saturday, October 26

Enhance your learning at any of the postgraduate courses, focusing on specific topics to deliver the relevant clinical information you need to make informed decisions with your patients. Postgraduate courses include:

- A Case-Based Review of

Critical Care: Why Didn't They Tell Me This in Fellowship?

- Advanced Critical Care Echocardiography
- Interventional Therapy for Pleural Disease: Evidence-Based Practice
- Pulmonary Literature Review
- Sleep Medicine Literature Review

• 21st Annual Assembly of the American Association for Bronchology and Interventional Pulmonology

Program Highlights

The CHEST 2013 program will connect you to education opportunities that optimize the clinical decisions you make. The relevant sessions and community of innovative problem-solvers in attendance promise to inspire and energize you. Don't miss these highlights:

General Sessions

Sunday, October 27 - Thursday, October 31

Choose from more than 300 sessions, offered in a variety of instructional formats.

Opening Sessions

Sunday, October 27 - Monday, October 28

Attend opening sessions featuring keynote speakers, Jim Collins and Chris Draft.

ACCP Simulation Center

Sunday, October 27 - Wednesday, October 30

Practice your clinical skills in a hands-on learning environment.

Ticketed Sessions

Clinical Resource Center

Monday, October 28 - Wednesday, October 30

Don't miss the showcase of diagnostic and treatment solutions for optimal patient care.

Play Time!

Fall is the perfect time to visit Chicago. Fewer crowds, colorful scenery, and cooler temperatures make it a popular destination during the vibrant, autumn months. And, it's family friendly. If you have free time during CHEST, be sure to check out what the city has to offer at ChooseChicago.com.

Learn more about CHEST 2013 and registration opportunities at chestmeeting.chestnet.org.

This Month in CHEST: Editor's Picks

BY DR. RICHARD S. IRWIN,
MASTER FCCP

Posttraumatic Stress Disorder in Survivors of Acute Lung Injury: Evaluating the Impact of Event Scale-Revised. By Dr. O. J. Bienvenu et al.

Ventilator-Associated Tracheobronchitis in a Mixed Medical/Surgical Pediatric ICU. By Dr. V. S. Simpson et al.

Does Autotitrating Positive Airway Pressure Therapy Improve Postoperative Outcome in Patients at Risk for Obstructive Sleep Apnea Syndrome? A Randomized Controlled Clinical Trial. By Dr. S. M. O'Gorman et al.

SPECIAL FEATURE

COPD Surveillance—United States, 1999-2011. By Dr. E. S. Ford et al.

POINT/COUNTERPOINT EDITORIAL

Should Board Certification Be Required for Sleep Test Interpretation?

Yes – Dr. S. A. Fleishman et al.

No – Dr. Richard D. Simon Jr.

Rebuttal from Dr. Fleishman et al.

Rebuttal from Dr. Simon.



NETWORKS: Research outcomes, Choosing Wisely, Home Care

Clinical Research

Identifying good outcomes for clinical research

For clinicians and patients, the appropriate selection of endpoints or outcomes in clinical research is important. Positive, or in certain circumstances negative, results, provide evidence about the efficacy, safety, and risks and benefit ratio of potential treatments for the disease in question.

Outcome selection is usually influenced by the study design and the resources allocated for the study and should be selected in a manner that maximizes the usefulness and interpretation of the results. In addition, outcome selection should be balanced with the natural scientific desire to achieve faster results, safety and efficacy issues, and the need to obtain meaningful data that are internally and externally valid. Endpoints that are less definitive may allow for shorter studies and easier ascertainment but may not yield useful or meaningful information in regards to how the study intervention would save lives and decrease morbidity by promoting health.

Historically, we have relied primarily

on traditional biomedical measures, such as the results of laboratory tests and changes in other metrics or crude outcomes, such as mortality, to try to determine whether a health intervention is necessary and whether it is successful. We have discovered, however, that when we use only these mea-



asures, we and the scientific community may miss many of the outcomes that may also matter most to patients. Hence, outcomes in clinical research must also measure how patients func-

tion and their experiences with care. Over the last decade, we have observed a trend toward researchers selecting outcomes that matter to patients such as: the quality of life, functionality, and cognition (Mikkelsen et al. *Am J Respir Crit Care Med.* 2012;185[12]:1307).

For the future, it is imperative that researchers design studies that will have a high yield in these domains as much as on mere survival.

The scientific method demands a rigorous approach. Identifying problems and testable hypotheses is important, but at the time of obtaining meaningful results that matter to patients, choosing the right outcomes becomes of vital importance.

*Dr. Fred Rincon, FCCP
Steering Committee Member*

Critical Care

Choosing Wisely ... in critical care medicine

The Choosing Wisely campaign is an effort sponsored by the American Board of Internal Medicine (ABIM) Foundation to “help physicians and patients engage in conversations about the overuse of tests and procedures

and support physician efforts to help patients make smart and effective care choices.” Major physician professional societies have partnered with consumer groups, led by *Consumer Reports*, in this attempt to improve the quality and safety of health care in America.

Representatives of physician professional societies gather to create Top 5 lists, which consist of five specific evidence-based recommendations of things physicians and patients should question in order to make wise care decisions on an individualized basis. For example, the list of the American College of Physicians includes a recommendation that internists “Don’t obtain preoperative chest radiography in the absence of a clinical suspicion for intrathoracic pathology.” The first of these lists was released in April 2012.

In the fall of 2012, under the leadership of Dr. Scott Halpern of the University of Pennsylvania, representatives of the American College of Chest Physicians, the Society of Critical Care Medicine, and the American Thoracic Society gathered to begin work on a Top 5 list for critical care medicine. Representing the College

Continued on following page



New This Year

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Pulmonary Board Practice Exam and Assessment for Attendees of ACCP Pulmonary Medicine Board Review 2013

Advance your board review preparation by taking the Pulmonary Board Practice Exam and Assessment before attending ACCP Pulmonary Medicine Board Review 2013, August 28-September 1, in San Antonio, Texas. Immediately after completing the exam, you will receive an analysis of your score by content area, helping you understand your knowledge gaps.

- Attend the board course better prepared.
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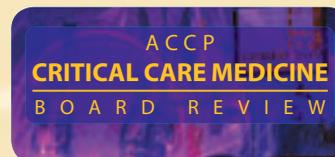
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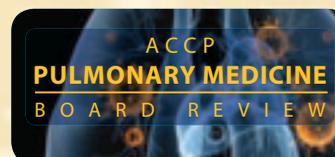
Rely on the ACCP, the leader in board review curriculums, for comprehensive review programs of proven success. World-renowned clinicians present exam-focused content to offer relevant board preparation courses that make the best use of your study time. Save these dates.



ACCP Sleep Medicine Board Review 2013
August 23 - 26
San Antonio, Texas
Exam Date: October 16



ACCP Critical Care Medicine Board Review 2013
August 23 - 26
San Antonio, Texas
Exam Date: October 9



ACCP Pulmonary Medicine Board Review 2013
August 28 - September 1
San Antonio, Texas
Exam Date: October 8



Still Time to Register
boardreview.chestnet.org

Continued from previous page

were Drs. Curt Sessler of Virginia Commonwealth University and Dr. Robert Hyzy of the University of Michigan. Over the next few months, through the leadership of Dr. Halpern, an initial list of more than 12 potential recommendations was whittled down to a list of five final recommendations.

The recommendations were reviewed and later endorsed by each participating professional society, including the Critical Care NetWork of the ACCP. The ABIM plans to announce the list, along with the lists of several other medical specialties, this fall. Look for a lively and engaging session in Chicago at CHEST 2013 entitled Choosing Wisely in Critical Care Medicine, which is being chaired by Dr. Halpern. For additional details on the Choosing Wisely campaign, see choosingwisely.org.

Dr. Robert Hyzy, FCCP
Steering Committee Member

Home Care

Acute care to home

Envision the use of bundled payments to address physician myopia, bringing home care into focus:

In a fee-for-service world, US health

care institutions are encouraged to provide services without regard to cost or outcomes. In 2009, the Jencks report highlighted that COPD and pneumonia were important medical diagnoses driving high 30-day readmission rates.¹ Since that time, multiple care transition plans have been investigated. One example, the “DASH” program in western Pennsylvania, reports a reduction in 30-day readmission rates for COPD from 25% to less than 5%.² This plan integrates the hospitals, postacute care facilities, and home health care in a “pull in” model of empowerment to address symptoms and maintain self-care. There is a focus on home-based care using respiratory therapists, pulmonary rehabilitation, and durable medical equipment providers.

This year, JAMA published three trials studying these issues on a larger stage. These studies emphasized the need to create better patient center models of care limiting fragmentation to support a transition from acute care to home. These studies highlight that the current system is myopic, with care providers that are incentivized to develop care plans that look no further than the room in which they sit.³

This month, The Medicare Payment Advisory Commission released a report with a new vision for pro-

viding home-based medical care. It emphasizes a limitation of traditional fee-for-service care replacing it with bundled payments encouraging hospitals to partner with post-acute care and home care providers to provide care plans for patients with chronic illness focused on ultimate success in a home environment.⁴

Dr. Lisa Wolfe, FCCP
Chair

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For more information and to purchase a paver, contact jdavies@chestnet.org.

CHEST ‘Impact Factor’ increases

The new Thomson Reuters Journal Citation Report Impact Factor (IF) numbers 2012 were released in mid-June, and show that the CHEST IF for 2012 increased from 5.25 to 5.85, ranking 4th for respiratory journals and 3rd in critical care in those categories.

CHEST was particularly pleased to see that it ranks first in the Immediacy Index in both categories. This is a measure of how quickly articles from

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Read more at “About CHEST” on the Journal site.

See the graphic below for numbers for CHEST from this year’s Journal Citation Report.

Measurement	Value	Rank in Respiratory	Rank in Critical Care
Impact Factor	5.85	4th	3rd
5-Year Impact Factor	6.420	3rd	2nd
Immediacy Index	3.394	1st	1st
Article Influence Score	2.188	3rd	2nd
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Baylor Dallas is a nursing Magnet hospital and Level I trauma center with nearly 40,000 admissions annually, and 1,200 physicians on the medical staff. The hospital is home to a renowned transplant program with surgical teams that performed 282 transplantations in the last 11 months. This includes the liver, kidney, pancreas, heart, lung and islet cell programs at Baylor University Medical Center (BUMC). BUMC educates 220 residents and fellows per year in 30 training programs and serves as a 3rd and 4th year training site for Texas A&M Health science Center College of Medicine.

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Interested candidates may contact Kristen Chapman for additional details. No J-1 or H-Visa sponsorships.

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Early adenotonsillectomy does not improve attention

BY MARY ANN MOON

IMNG Medical News

Compared with watchful waiting, early adenotonsillectomy did not significantly improve attention or executive function as measured by neuropsychological testing in school-aged children with obstructive sleep apnea syndrome, according to a new report.

However, early surgery did markedly improve polysomnographic abnormalities, as well as parent- and teacher-reported measures of behavior, executive function, and sleep symptoms, compared with watchful waiting, said Dr. Carole L. Marcus, director of the sleep center at Children's Hospital of Philadelphia, and her associates.

"We observed no significant differ-

ence between the two groups in the change from baseline to follow-up in our primary outcome, the attention and executive-function score of the NEPSY [Developmental Neuropsychological Assessment]; thus, our trial is a negative one. However, other tests showed evidence of changes in behavior," noted Dr. Marcus and her associates in the Childhood Adenotonsillectomy Trial (CHAT).

The findings were published online in the *New England Journal of Medicine* (2013 May 21 [doi:10.1056/NEJMoa1215881]).

CHAT involved 453 children aged 5-9 years treated at seven academic sleep centers, who underwent standardized polysomnographic assessments and extensive neuropsychological testing and answered sleep and quality of life-related questionnaires.

The children were randomly assigned to undergo adenotonsillectomy within 1 month (226 patients) or to be followed with watchful waiting (227 control subjects), and were formally assessed 7 months later. Their cognitive and behavioral scores were close to population means. A similar number of children in each group used nasal glucocorticoids or montelukast for allergic rhinitis or asthma. About half of the children in each group were overweight or obese.

The change in the attention and executive-function score on the NEPSY (primary outcome) was greater in children who underwent adenotonsillectomy than in controls, but the difference did not reach statistical significance. However, outcomes were significantly better with surgery than with watchful waiting on measures of obstructive ap-

nea-hypopnea, oxygen desaturation index, hypercapnia, sleep arousal index, and percentage of sleep time in light sleep. More children who underwent early adenotonsillectomy (79%) achieved normalization of the obstructive sleep apnea syndrome, compared with control subjects (46%).

Adenotonsillectomy improved outcomes to a significantly greater degree than did watchful waiting on the Conners' Rating Scale assessing restlessness, impulsiveness, and emotional lability, and on all other measures of behavior and quality of life. Changes were clinically significant.

CHAT was supported by the National Institutes of Health. Dr. Marcus reported receiving research equipment from Philips Respironics and Ventus Medical; her associates reported ties to industry sources.

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Obesity, apnea: An undertreated mix

Syndrome from page 1

prevalence of OHS varies widely between different studies, and current data are most likely to be an underestimation because many cases of the disease remain unrecognized. According to a recent review, the overall prevalence of OHS varies between 10 and 20% in outpatient populations (Mokhlesi et al. *Chest*. 2007;132[4]:1322) but is reported to be as high as 31% among hospitalized patients (Nowbar et al. *Am J Med*. 2004;116[1]:1).

The reason why less than one-third of morbidly obese patients with OSA develop diurnal hypercapnia remains unclear. Possible contributors to disease development include



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Positive airway pressure, both as CPAP and bilevel pressure, is the most-studied therapy for patients with obesity hypoventilation syndrome.

both altered central respiratory drive and increased mechanical load on the respiratory muscles due to severe obesity. Patients with OHS have been noted to have increased levels of leptin compared with their eucapnic counterparts. This is despite the fact that this protein acts as a respiratory stimulant, suggesting that leptin resistance may contribute to their hypoventilation. In addition, there is evidence that chronic severe OSA can induce minute but progressively greater effects on renal bicarbonate retention over time, leading to impaired ventilatory compensation for carbon dioxide retention (Norman et al. *J Appl Physiol*. 2006;100[5]:1733).

Screening for OHS

Because arterial blood gas (ABG) sampling is not routinely performed in obese patients unless physicians have a high clinical suspicion for OHS, less invasive screening modalities are needed in order to aid in the early diagnosis of disease. Serum bicarbonate may be one option since levels are elevated in patients with OHS secondary to their chronic respiratory acidosis

and is readily available as part of a basic chemistry panel. In one study of OSA patients, a serum bicarbonate >27 mEq/L was found to have a high sensitivity of predicting OHS (92%) but a low specificity (50%) (Mokhlesi et al. *Sleep Breath*. 2007;11[2]:117). Only two polysomnographic parameters were associated with a statistically significant increased risk of OHS, apnea-hypopnea index (AHI), and nadir oxygen saturation during sleep. Combining all of these variables into one prediction rule did not achieve a positive predictive value of greater than 50% for OHS, indicating that patients in a high-risk group still need formal evaluation by ABG.

Another attractive option is transcutaneous CO₂ monitoring, which is becoming increasingly available in sleep labs. The role of this modality in screening for OHS has not been extensively studied, though readings seem to correlate well with arterial PCO₂ in obese patients. Current recommendations state that transcutaneous PCO₂ values should be confirmed with arterial blood gas testing (Berry RB et al. *J Clin Sleep Med*. 2010;6[5]:491). At this time, routine use during diagnostic polysomnography is probably not appropriate as a mechanism for diagnosing hypoventilation. Based upon available data, it seems appropriate to perform ABG analysis to confirm the presence of hypercapnia in obese patients with sleep-disordered breathing who have a bicarbonate level above 27 mEq/L and/or diurnal hypoxemia (pulse oximetry < 94%). In superobese patients (BMI > 50 kg/m²) who are scheduled for bariatric surgery (Mechanick JL et al. *Obesity*. 2009;17: S3), a thorough evaluation including laboratory testing (complete blood count, thyroid-stimulating hormone), chest radiographs, and complete pulmonary function tests should also be performed to exclude other etiologies, which could contribute to CO₂ retention in these subjects.

OHS-associated morbidity and mortality

The risk of cardiovascular events is elevated in obese patients with OSA, and the presence of OHS in these patients leads to a further increase in morbidity and mortality (Berg et al. *Chest*. 2001;120[2]:377). Compared with patients with OSA alone,

patients with OHS are sleepier during the day and are more likely to have severe exertional dyspnea, lower extremity edema, pulmonary hypertension, and cor pulmonale at the time of initial diagnosis (Kessler et al. *Chest*. 2001;120:369). Patients with OHS use great quantities of health-care resources and have high rates of ICU admission, mechanical ventilation, and long-term care; 18 months after hospitalization, mortality was more than doubled in patients with OHS compared with obese control subjects (23% vs 9%) (Nowbar et al. *Am J Med*. 2004;116[1]:1). Alarming, despite having received a diagnosis of OHS while hospitalized, only 13% of these patients were discharged using positive airway pressure therapy (PAP) therapy for their disease.

The role of positive airway pressure in OHS

PAP (both as CPAP and bilevel pressure) is the most-studied and well-proven therapy for patients with OHS. This treatment corrects sleep-disordered breathing and may partially reverse nocturnal hypoventilation by improving carbon dioxide clearance from inadequately ventilated alveoli. When implementing therapy for stable patients with OHS during in-lab titration, CPAP is initiated first, with levels increased to eliminate any evidence of airway obstruction (including flow limitation), though CPAP alone may not be sufficient to alleviate nocturnal hypoventilation. If oxygen saturation remains below 90% despite resolution of obstructive events, patients can be switched to bilevel PAP, with inspiratory pressure increased over the CPAP until oxygen saturation improves; a pressure difference of at least 6 to 7 cm H₂O is generally required. Other indications for bilevel pressure include patients presenting with an acute decompensation of their chronic respiratory failure and patients who are intolerant of the level of CPAP required to completely alleviate their obstructive physiologic condition. Oxygen supplementation can be considered if pressure support needs to exceed 8 to 10 cm H₂O. The role of transcutaneous carbon dioxide monitoring during PAP titration in patients with OHS has not been well-studied but would seem to be a reasonable option to help identify the most appropriate level of therapy (Chau et al. *Clin Sleep Med*. 2013;8[1]:135).

Average volume-assured pressure support (AVAPS, Philips-Respironics) is a newer bilevel PAP modality with a variable inspiratory pressure, which varies between a preset minimum and

maximum level to deliver a targeted tidal volume (usually set at 8 mL/kg ideal body weight), using a built-in algorithm. While AVAPS has been shown to provide better ventilation and gas exchange compared with standard bilevel PAP therapy, no other clear advantage to patients has been demonstrated (Murphy et al. *Thorax*. 2012;67:727). Further studies are needed to identify predictors, which could identify patients with OHS who can be adequately treated with CPAP, as opposed to those who benefit more from bilevel pressure or AVAPS.

Improved outcomes with positive airway pressure

PAP therapy improves diurnal gas exchange, daytime sleepiness, and quality of life, as well as sleep quality (Piper et al. *Thorax*. 2008[5];63:395); therapy also leads to a decrease in health-care utilization and hospitalization rates (Berg et al. *Chest*. 2001;120[2]:377) and improves survival, with 1-, 2- and 5-year survival rates of 97.5%, 93%, and 77.3%, respectively (Priou et al. *Chest*. 2010;138[1]:84). A recent prospective study examined the role of protocolized bilevel PAP therapy in patients with acute hypercapnic respiratory failure caused by OHS (Carrillo et al. *Am J Respir Crit Care Med*. 2012;186[12]:1279); compared with those with COPD, patients with OHS had a lower rate of late PAP failure (13% vs 7%, $P = .037$), hospital mortality (18% vs 6%, $P < .001$), and higher 1-year survival (odds ratio = 1.83, $P = .002$). Despite the proven benefit, only 55% of the patients with OHS were discharged with PAP therapy, once again demonstrating the importance of appropriate treatment and follow-up in these patients.

Conclusion

Despite signs of increasing prevalence, OHS remains an underrecognized and undertreated condition. Though there are recent data confirming the advantages of treatment with PAP therapy in affected patients, the percentage receiving therapy remains alarmingly low; whether this is due to a lack of recognition or a lack of awareness of the benefits of therapy is unclear. As sleep specialists, we need to be more aggressive at diagnosing and treating this condition, leading to better outcomes for our sickest patients.

Dr. Andreea Antonescu-Turcu, FCCP
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